

# MEDICARE MANAGED CARE FROM THE BENEFICIARY'S PERSPECTIVE

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## I. INTRODUCTION

Whatever future legislation to change the Medicare program comes out of the current debate over the 1997 federal budget, the Medicare program will continue to move toward capitated managed care for Medicare beneficiaries. Capitated managed care is fast becoming the predominant model for the delivery of health care services in the United States today as both public and private payers seek to control the escalating costs of health care services. Although coming lately to capitated managed care,<sup>1</sup> Medicare, like the rest of the health care system, will ultimately embrace capitated managed care for most Medicare beneficiaries. The question is not whether, but when and how. This Article offers some thoughts on how beneficiaries can and should be protected as Medicare moves its beneficiaries from delivery systems with fee-for-service providers toward managed health plans paid on a capitated basis.

This Article first reviews the history of the Medicare program and how the program has historically approached managed care. This history is important, for it reflects some of the appropriate caution that Congress and the Executive Branch in both Republican and Democratic administrations have exhibited toward health maintenance organizations (HMOs) for Medicare beneficiaries. Second, the Article reviews Medicare's experience to date with capitated managed care including key legislative enactments and procedural methods for protecting beneficiaries in capitated health plans. Next, the Article reviews the proposals for reform of the Medicare program before Congress today and assesses their merits in terms of protecting the entitlement of beneficiaries to statutory health benefits under the Medicare program. Finally, the Article addresses the central question of what procedural arrangements ought to be in place in Medicare managed care plans to

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<sup>1</sup> See *infra* notes 73-77 and accompanying text.

assure the protection of all Medicare beneficiaries. In so doing, the article draws heavily on my previous scholarship on the Medicare program and procedural protections for consumers in today's health care system.<sup>2</sup>

## II. BACKGROUND ON THE MEDICARE PROGRAM

Congress enacted the Medicare program in 1965 with the strong support of President Lyndon Johnson.<sup>3</sup> The program was another linchpin in the Social Security system established under the democratic presidency of Franklin Roosevelt. In the 1940s, President Harry Truman had tried to enact health insurance for the aged and failed. President John Kennedy and Vice President Lyndon Johnson had stressed health insurance for the elderly as a major campaign theme in 1960. At that time, the problem of access to quality health care services for the aged was especially severe. In 1963, although the aged had a greater risk of illness and far lower income than other population groups, only 56% had health insurance.<sup>4</sup> Passage of Medicare was a Democratic Party triumph. President Johnson signed the bill on the porch of President Truman's home in Independence, Missouri, stating at the time: "No longer will older Americans be denied the healing powers of modern medicine. No longer will illness crush and destroy the savings that they have so carefully put away over a lifetime so that they might enjoy dignity in later years."<sup>5</sup>

Over the years, the Medicare program has grown and become

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<sup>2</sup> See generally Eleanor D. Kinney, *Procedural Protections for Patients in Capitated Health Plans*, \_\_\_ AM. J. OF L. & MED. \_\_\_ (1996) (in press); Eleanor D. Kinney, *Resolving Consumer Grievances in a Managed Care Environment*, \_\_\_ HEALTH MATRIX \_\_\_ (1995) (in press); Eleanor D. Kinney, *Protecting Consumers and Providers under Health Reform: An Overview of the Major Administrative Law Issues*, 5 HEALTH MATRIX 83 (1995); Eleanor D. Kinney, *The Role of Judicial Review Regarding Medicare and Medicaid Program Policy: Past Experience and Future Expectations*, 35 ST. LOUIS U. L.J. 759 (1991); Eleanor D. Kinney, *In Search of Bureaucratic Justice in the Medicare Program: Adjudicating Medicare Home Health Benefits in the 1980s*, 42 ADMIN. L. REV. 251 (1990); Eleanor D. Kinney, *Setting Limits: A Realistic Assignment for the Medicare Program?*, 33 ST. LOUIS U. L.J. 631 (1989); Eleanor D. Kinney, *National Coverage Policy Under the Medicare Program: Problems and Proposals for Change*, 32 ST. LOUIS U. L.J. 869 (1988); Eleanor D. Kinney, *The Medicare Appeals System for Coverage and Payment Disputes: Achieving Fairness in a Time of Constraint*, 1 ADMIN. L.J. 1 (1987).

<sup>3</sup> Social Security Amendments of 1965, § 101, Pub. L. No. 79-97, 79 Stat. 286 (1965) (codified at 42 U.S.C. §§ 1395-1395ccc (1988 & Supp. V 1993)) (adding Title XVIII: Health Insurance for the Aged to the Social Security Act).

<sup>4</sup> Marian Gornik et al., *Twenty Years of Medicare and Medicaid: Covered Populations, Use of Benefits, and Program Expenditures*, HEALTH CARE FIN. REV. 13, 14 (1985 Supp.).

<sup>5</sup> Remarks at the Signing of the Medicare Bill, 2 PUB. PAPERS 811, 813 (July 30, 1965).

a linchpin in the social safety net for all Americans. The Medicare program now serves 36.3 million Americans, or just over seven percent of the population.<sup>6</sup> An estimated twenty-nine million persons were actual users of the Medicare program during 1993.<sup>7</sup> The average per enrollee expenditure for the Medicare program in 1992 was \$3,391.<sup>8</sup> Over half of Medicare beneficiaries had payments of less than \$500 per year, while only 9.8 percent of Medicare beneficiaries (3.5 million) incurred payments of \$10,000 or more.<sup>9</sup>

In 1993, federal expenditures for the Medicare program were \$151 billion.<sup>10</sup> Medicare expenditures accounted for 10% of the federal budget in Fiscal Year 1995.<sup>11</sup> Medicare expenditures are increasing dramatically compared to other components of health spending. The rate of increase in Medicare expenditures between 1980 and 1992 was 11.5%, a figure lower than in earlier decades.<sup>12</sup> Although substantial reforms were made in the way in which the Health Care Financing Administration (HCFA) paid hospitals and physicians in the 1980s,<sup>13</sup> these inflationary trends in Medicare expenditures continue to cause concern. Indeed, it is estimated that the Medicare Hospital Insurance Trust Fund, which finances Part A of the Social Security wage tax, will be exhausted in 2002.<sup>14</sup> These trends in Medicare expenditures are driving the push for capitated managed care for Medicare beneficiaries.

#### A. *Medicare Benefits, Coverage and Administration*

The Medicare program provides basic health insurance to the

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<sup>6</sup> Katharine R. Levit et al., *National Health Expenditures, 1993*, 16 HEALTH CARE FIN. REV. 247, 263 (1994).

<sup>7</sup> OFFICE OF RESEARCH & DEMONSTRATIONS, HEALTH CARE FIN. ADMIN., DEPT. OF HEALTH & HUMAN SERVS., MEDICARE AND MEDICAID STATISTICAL SUPPLEMENT, HEALTH CARE FIN. REVIEW 1, 24 (1995).

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*; see Statement of Marilyn Moon, Senior Fellow, The Urban Institute, Proposed Changes in the Structure of Medicare Under the Balanced Budget Act of 1995 (Jan. 17, 1996) (discussing proposed changes and their implications); Statement of Bruce Vladeck, Administrator, Health Care Fin. Admin. to the Subcommittee on Health, House Committee on Ways and Means (Feb. 10, 1995) (addressing the subcommittee regarding the current state and future of the Medicare program).

<sup>10</sup> Levit et al., *supra* note 6, at 262.

<sup>11</sup> See generally OFFICE OF MANAGEMENT AND BUDGET, BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 1996: A CITIZEN'S GUIDE TO THE FEDERAL BUDGET (1995).

<sup>12</sup> MEDICARE AND MEDICAID STATISTICAL SUPPLEMENT, *supra* note 7, at 16.

<sup>13</sup> See *infra* notes 64-65 and accompanying text.

<sup>14</sup> BOARD OF TRUSTEES OF THE SOCIAL SECURITY AND MEDICARE TRUST FUNDS, STATUS OF THE SOCIAL SECURITY AND MEDICARE PROGRAMS—A SUMMARY OF THE 1995 ANNUAL REPORTS (1996) (available via World Wide Web at [http://www.ssa.gov/policy/trustees\\_summary\\_1995.html](http://www.ssa.gov/policy/trustees_summary_1995.html)).

elderly, severely disabled, and people with End Stage Renal Disease.<sup>15</sup> The program is comprised of two separate programs. Part A, the Hospital Insurance Program, provides hospital and related services and is financed through a payroll tax on all workers.<sup>16</sup> Part B, the Supplementary Medical Insurance Program, provides physician and outpatient services and is financed by premiums from beneficiaries.<sup>17</sup> Medicare also pays for these services through HMOs and other capitated managed care plans as described below.<sup>18</sup>

Medicare is administered by the HCFA in the Department of Health and Human Services (DHHS), which in turn contracts with private insurers to handle claims, appeals, and other matters. For fee-for-service Medicare, fiscal intermediaries administer payments and claims from Part A providers; carriers administer payment and claims for Part B providers.<sup>19</sup> Medicare also contracts with private peer review organizations to review the quality of care accorded Medicare beneficiaries, handle beneficiary appeals arising out of hospitalization, and perform other oversight functions for the Medicare program.<sup>20</sup>

### 1. Medicare Benefits

The benefits provided under Part A, the hospital insurance component, include ninety days of basic hospitalization for each spell of illness.<sup>21</sup> Part A coverage also includes a stay of 100 days in a skilled nursing facility following a hospitalization,<sup>22</sup> an unlimited number of home health agency visits if the beneficiary is confined to home and in need of skilled nursing care,<sup>23</sup> and some limited hospice services for patients who are terminally ill.<sup>24</sup> When patients avail themselves of the hospital benefit, they must pay a deductible amounting to the cost of the first day of hospitalization; in addition, some coinsurance is required after the sixtieth day of a hospital stay.<sup>25</sup> Coinsurance is also required for skilled nursing

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<sup>15</sup> 42 U.S.C. §§ 1395-1395ccc (1988 & Supp. V 1993).

<sup>16</sup> 42 U.S.C. § 1395i (1988).

<sup>17</sup> See *id.*

<sup>18</sup> See *supra* notes 79-85 and accompanying text.

<sup>19</sup> 42 U.S.C. §§ 1395h & u.

<sup>20</sup> See *supra* note 62 and accompanying text.

<sup>21</sup> 42 U.S.C. § 1395d.

<sup>22</sup> *Id.*

<sup>23</sup> See *id.* § 1395x(m) (defining home health services).

<sup>24</sup> *Id.* § 1395d(d).

<sup>25</sup> *Id.* § 1395e.

services, but not for home health services.<sup>26</sup>

The benefits furnished under Part B, the supplementary medical insurance component, include physician services plus a wide variety of other medical services provided on an outpatient basis.<sup>27</sup> Finally, an increasingly important and costly Part B benefit is the lease or purchase of durable medical equipment.<sup>28</sup> There is no limitation on the number of physician services which fall under Part B coverage.<sup>29</sup> Enrollees pay an annual deductible of \$100 and pay 20% coinsurance on most covered services incurred during the year.<sup>30</sup>

## 2. Medicare Coverage Policy

Coverage is an important concept in understanding Medicare benefits, particularly the disputes over benefits that arise between beneficiaries, providers, and the Medicare program. In effect, coverage defines the type and the amount of health care benefits for which the Medicare program will pay, as well as the conditions that must be met in order to receive payment. The Social Security Act specifies certain types of services that are expressly excluded from coverage under the Medicare program.<sup>31</sup> For both Part A and Part B, such services include physicals, immunizations, eyeglasses and hearing aids, personal comfort items, and cosmetic surgery.<sup>32</sup>

One is entitled to coverage only if two conditions are met. First, the services must be "reasonable and necessary" for the diagnosis and treatment of an illness or injury.<sup>33</sup> Second, the services rendered must not be covered by another public insurance program.<sup>34</sup>

Currently, the Medicare program makes coverage policy in a fairly informal process that has generated considerable criticism

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<sup>26</sup> *Id.* § 1395e(a)(3).

<sup>27</sup> *Id.* § 1395k. These include services provided in hospital outpatient departments and rural health clinics; outpatient surgery; diagnostic x-ray and laboratory services; rehabilitative services; physical, occupational, and speech therapy; and services ordered by a physician but performed by physicians' assistants and nurse practitioners. *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* § 1395y(a)(1) (listing those items and services explicitly excluded from coverage).

<sup>30</sup> *Id.* §§ 1395l(a)-(b) (explaining payment of benefits in terms of amounts paid and deductible provisions).

<sup>31</sup> *See id.* § 1395y (listing exclusions from coverage).

<sup>32</sup> *See id.*

<sup>33</sup> *Id.* § 1395y(a)(1).

<sup>34</sup> *Id.* §§ 1395y(a)(2)-(3).

over the years.<sup>35</sup> HCFA publishes the decisions on coverage on new technologies and other specific items and services in its *Medicare Coverage Issues Manual*<sup>36</sup> and other Medicare program manuals. In 1989, HCFA published a proposed rule outlining its coverage policy-making procedures.<sup>37</sup> HCFA has not yet officially adopted this rule. In August 1989, HCFA published a notice on its procedures for promulgating national coverage policy and included major coverage determinations.<sup>38</sup>

In 1986, Congress created an explicit bar to procedural challenges to Medicare national coverage determinations<sup>39</sup> on the grounds that current procedures for making national coverage determinations and the need to preserve the scientific integrity of national coverage policy rendered the procedures required by the Administrative Procedure Act (APA) unnecessary.<sup>40</sup> Congress also required courts to remand contested national coverage policies to the Secretary of the DHHS for amplification of the record.<sup>41</sup> Courts have generally upheld HCFA national coverage determinations, according great deference to DHHS and its expert decision-making process.<sup>42</sup> However, in 1987, the Administrative Conference of the United States recommended changes regarding the

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<sup>35</sup> See generally Timothy P. Blanchard, "Medical Necessity" Denials as a Medicare Part B Cost-Containment Strategy: *Two Wrongs Don't Make It Right or Rational*, 34 ST. LOUIS U. L.J. 939 (1990); Eleanor D. Kinney, *National Coverage Policy Under the Medicare Program: Problems and Proposals for Change*, 32 ST. LOUIS U. L.J. 869 (1988); see also generally LINDA A. BERGTHOLD & WILLIAM M. SAGE, MEDICAL NECESSITY, EXPERIMENTAL TREATMENT AND COVERAGE DETERMINATIONS: LESSONS FROM NATIONAL HEALTH CARE REFORM (Oct. 1994); Mark A. Hall & Gerald F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637 (1992).

<sup>36</sup> HEALTH CARE FIN. ADMIN, MEDICARE COVERAGE ISSUES MANUAL (HCFA Pub. 6) (1995) reprinted in Medicare & Medicaid Guide (CCH) ¶ 27,201 (1995).

<sup>37</sup> Proposed Rule, Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4302 (proposed Jan. 30, 1989).

<sup>38</sup> General Notice, Medicare Program; National Coverage Decisions, 54 Fed. Reg. 34,555 (1989).

<sup>39</sup> See 42 U.S.C. § 1395ff(b) (1988 & Supp. V 1993).

<sup>40</sup> H.R. Rep. No. 1012, 99th Cong., 2d Sess. 350-51 (1986). But see National Coverage Determinations under the Medicare Program, 1 C.F.R. §§ 305.87-8 (1993); see also generally Kinney, *National Coverage Policy*, *supra* note 2.

<sup>41</sup> See 42 U.S.C. § 1395ff(b)(3)(C) (1988 & Supp. V 1993).

<sup>42</sup> See, e.g., *Fiedrich v. Secretary of HHS*, 894 F.2d 829 (6th Cir. 1990) (recognizing that the DHHS is charged with establishing national standards to ensure uniformity and equality in the administration of Medicare and upholding the Secretary's coverage determination); *Goodman v. Sullivan*, 891 F.2d 449 (2d Cir. 1989) (recognizing that the Secretary of DHHS may regulate the Medicare program by enacting regulations concerning Medicare reimbursement); *Wilkins v. Sullivan*, 889 F.2d 135 (7th Cir. 1989) (deferring to the DHHS Secretary's authority to interpret Medicare statutes).

procedures for making national coverage policy as well as judicial review of national coverage policy.<sup>43</sup>

### B. *Some Important History*

When Congress and the Johnson Administration enacted the Medicare program in 1965,<sup>44</sup> they deliberately maintained the fee-for-service payment system for all providers out of the concern that the health care providers in the Medicare program would otherwise be unwilling to participate in the Medicare program.<sup>45</sup> Indeed, the opening section of the Social Security Amendments of 1965 explicitly provided:

Nothing in this title shall be construed to authorize any federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.<sup>46</sup>

Congress specified that hospitals would be paid the "reasonable cost of covered services" according to principles used by private insurance companies.<sup>47</sup> The Department of Health, Education and Welfare (DHEW) used the principles of cost reimbursement that Blue Cross and Blue Shield had developed for payment of hospitals under their programs.<sup>48</sup> The only additional requirement that Congress imposed was that hospitals conduct "utilization review" of their care of Medicare patients.<sup>49</sup>

Although a comparatively mild requirement by modern stan-

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<sup>43</sup> See National Coverage Determinations Under the Medicare Program, *supra* note 40, § 305.87-8 (recommending changes regarding coverage and reimbursement); see also generally Kinney, *National Coverage Policy*, *supra* note 2.

<sup>44</sup> Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 291, (codified as amended at 42 U.S.C. §§ 1395-1395ccc (1988 & Supp. V 1993)).

<sup>45</sup> See ROBERT J. MYERS, *MEDICARE 1-84* (1970) (reviewing the legislative history of the Medicare program and the compromises with the provider community that influenced Medicare program design); JUDITH M. FEDER, *MEDICARE: THE POLITICS OF FEDERAL HOSPITAL INSURANCE 1-5* (1977) (reviewing the rationale for the basic design of the Medicare program).

<sup>46</sup> 42 U.S.C. § 1395 (1988 & Supp. V 1993)).

<sup>47</sup> See 42 U.S.C. § 1395x(v) (1988 & Supp. V 1993) (defining reasonable costs with regard to covered services).

<sup>48</sup> See generally DEPARTMENT OF HEALTH, EDUC., AND WELFARE, *PRINCIPLES OF COST REIMBURSEMENT* (1968).

<sup>49</sup> 42 U.S.C. § 1395x(k) (1988 & Supp. V 1993).

dards, this utilization review requirement was controversial.<sup>50</sup> It was imposed, however, because Congress and DHEW were concerned about the inflationary incentives in the Medicare payment system for hospitals.<sup>51</sup> Yet, utilization review was really the first effort of the federal government to impose some type of external "management" on the care of Medicare beneficiaries that was physician ordered.

The Medicare program had a very indirect relationship with physicians and, indeed, only paid physicians directly if patients "assigned" their claims to physicians.<sup>52</sup> Medicare paid for physicians' services on the basis of usual and customary charges.<sup>53</sup> This payment system was highly inflationary because it accorded physicians exclusive authority to determine charges for services along with the authority to control the volume of services provided to patients.

The Medicare program, along with Medicaid, generated enormous demand for health care services and with this increased demand came sharp and continuing increases in the cost of health care services.<sup>54</sup> The seriousness of the cost problem surfaced shortly after the inauguration of the Medicare programs when initial DHEW inflation projections exceeded all expectations.<sup>55</sup> Since 1970, curbing Medicare program costs has been the predominant policy issue for the Medicare program.

Congress and DHEW took steps to curb the inflation in Medicare expenditures. In the Social Security Amendments of 1972,<sup>56</sup> three important cost containment measures were introduced to curb health care cost inflation. The first was an expenditure cap on allowable hospital costs.<sup>57</sup> The second was a capital expenditure review program, the so-called Section 1122 program.<sup>58</sup> The third was the Professional Standards Review Organization (PSRO) program that established independent organizations of physicians to review utilization of hospital services for Medicare benefi-

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<sup>50</sup> See SYLVIA A. LAW, *BLUE CROSS: WHAT WENT WRONG?* 115-44 (2d ed. 1976).

<sup>51</sup> See SENATE COMM. ON FINANCE, 91ST CONG., 1ST SESS, REPORT OF THE STAFF, *MEDICARE AND MEDICAID—PROBLEMS, ISSUES, AND ALTERNATIVES* 17-18 (Comm. Print 1970) [hereinafter *MEDICARE AND MEDICAID*].

<sup>52</sup> See Social Security Amendments of 1965, § 101, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended at 42 U.S.C. § 1395u(b)(3) (1988)).

<sup>53</sup> 42 U.S.C. § 1395u(b)(3).

<sup>54</sup> Gornick et al., *supra* note 4, at 35-45.

<sup>55</sup> *MEDICARE AND MEDICAID*, *supra* note 51, at 3-4.

<sup>56</sup> Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1329 (codified as amended in 42 U.S.C. §§ 1395-1395ccc (1988 & Supp. V 1993)).

<sup>57</sup> See 42 U.S.C. § 1395x(v) (1988 & Supp. V 1993) (defining reasonable costs).

<sup>58</sup> Social Security Amendments of 1972, § 221, 86 Stat. 1386 (codified at 42 U.S.C. § 1320a-1).



ciaries.<sup>59</sup> These three programs represent the predominant regulatory approaches for controlling health care expenditures in a fee-for-services payment environment: (1) rate-setting; (2) capital expenditure review; and (3) utilization management.

These programs were extremely controversial when implemented in the early 1970s. Perhaps the most controversial—at least with physicians—was the PSRO program. Immediately upon implementation, the organized medical profession brought suit to challenge the constitutionality of the program.<sup>60</sup> The program was finally disbanded in the early 1980s by the Reagan Administration in conformity with campaign promises that presidential candidate Ronald Reagan had made to the medical profession.<sup>61</sup>

Yet, in 1982, Congress enacted the Peer Review Organization (PRO) program to oversee utilization under a reformed Medicare payment system for hospitals.<sup>62</sup> Congress was simply concerned that imposing tightened payment methodologies on hospitals—in advance of moving toward prospective payment of hospitals without regulating utilization of services by Medicare beneficiaries—would generate costly excess services and expenditures for the Medicare program.<sup>63</sup> Like the PSRO program, the PRO program required the DHHS to contract with physician organizations to review hospital utilization of Medicare beneficiaries. Managed care for Medicare was unequivocally launched.

In the 1980s, the major policy initiatives and changes for the Medicare program were payment reform to address undesirable incentives in fee-for-service medicine. In 1983, Congress, with support from the Reagan Administration, enacted the DRG prospective payment system for hospitals that paid a preset price based on the patient's diagnosis and medical condition.<sup>64</sup> Con-

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<sup>59</sup> 42 U.S.C. § 1395x(k) (1988 & Supp. V 1993) (creating a utilization review plan).

<sup>60</sup> *Association of Am. Physicians and Surgeons v. Weinberger*, 395 F. Supp. 125 (N.D. Ill. 1975), *aff'd*, 423 U.S. 975 (1975) (finding that the statute establishing the PSRO program did not bar physicians from practicing their profession and is not so patently arbitrary and totally lacking in rational justification as to be violative of the Due Process Clause of the Fifth Amendment to the Constitution).

<sup>61</sup> Omnibus Budget Reconciliation Act of 1981, § 2111, Pub. L. No. 97-35, 95 Stat. 357, 793 (codified as amended at 42 U.S.C. § 1320c-4 (1988)).

<sup>62</sup> Tax Equity and Fiscal Responsibility Act of 1982, §§ 141-50, Pub. L. No. 97-248, 96 Stat. 381 (codified as amended in 42 U.S.C. § 1320c (1988)); see generally Peter E. Dans et al., *Peer Review Organizations: Promises and Potential Pitfalls*, 31 NEW ENG. J. MED. 1131 (1985).

<sup>63</sup> *Peer Review Organizations: Hearings Before the Subcomm. on Health of the Senate Comm. On Finance*, 99th Cong., 1st Sess. 2 (1985).

<sup>64</sup> Social Security Amendments of 1983 § 601(e), Pub. L. No. 98-21, 97 Stat. 65 (codified as amended in 42 U.S.C. §§ 1395ww (1988)).

gress, with support of the Bush Administration, enacted a revised payment system for physician services in 1989 that paid physicians based on the time and resources involved in treating specific conditions rather than on a charge basis.<sup>65</sup>

Another important policy development that augmented the development of managed care was increased emphasis on Medicare coverage policy and quality improvement strategies. In the early 1980s, health services researchers published important findings in health services research on the effectiveness or "outcomes" of specific medical procedures.<sup>66</sup> Responding to these findings and exhibiting an increased interest in the use of coverage policy as a means to contain Medicare program cost and improve the quality and effectiveness of care accorded Medicare beneficiaries, DHHS launched a health services research initiative to expand research on outcomes of care.<sup>67</sup>

In 1989, Congress charged the newly-created Agency for Health Care Policy and Research (AHCPR) to support outcomes research on outcomes of specific medical procedures, and sponsor development of medical practice guidelines based on this research.<sup>68</sup> Third-party payers have used outcomes research on costly and widely-used medical procedures to define the content of medically necessary and appropriate care through development of medical practice guidelines, clinical standards, and quality assurance measures. The theory behind using outcomes research in this way is that cost savings can be achieved and quality improved by limiting coverage of health care services that do not have a significant impact on health outcomes.<sup>69</sup> HCFA and carriers are also becom-

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<sup>65</sup> Omnibus Budget Reconciliation Act of 1989 § 6102, Pub. L. No. 101-239, 103 Stat. 2111, 2169 (codified as amended at 42 U.S.C. § 1395w-4(a) (1988 & Supp. V 1993)).

<sup>66</sup> See generally Robert H. Brook & Kathleen N. Lohr, *Efficacy, Effectiveness, Variations, and Quality—Boundary-Crossing Research*, 23 MED. CARE 710 (1985); Mark R. Chassin, *Standards of Care in Medicine*, 25 INQUIRY 437 (1988); David M. Eddy, *Variations in Physician Practice: The Role of Uncertainty*, 3 HEALTH AFF. 74 (Summer 1984); John E. Wennberg, *Commentary: On Patient Need, Equity, Supplier-Induced Demand, and the Need to Assess the Outcomes of Common Medical Procedures*, 23 MED. CARE 512 (1985); John E. Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, 3 HEALTH AFF. 6 (1984).

<sup>67</sup> See generally William L. Roper, M.D., et al., *Effectiveness in Health Care: An Initiative to Evaluate and Improve Medical Practice*, 319 NEW ENG. J. MED. 1197 (1988).

<sup>68</sup> Omnibus Budget Reconciliation Act of 1989, § 6103, Pub. L. No. 101-239, 103 Stat. 2106, 2189 (1989) (codified as amended at 42 U.S.C. § 299 (1988 & Supp. V 1993)).

<sup>69</sup> See generally David M. Eddy & John Billings, *The Quality of Medical Evidence: Implications for Quality of Care*, 7 HEALTH AFF. 19 (Spring 1988); John E. Wennberg, *Improving the Medical Decision-Making Process*, 7 HEALTH AFF. 99 (Spring 1988); see also Arnold

ing more sophisticated in the use of medical practice guidelines, often based on DHHS funded outcomes research, to make scientifically-based coverage policy that may result in limits on coverage of certain medical procedures for Medicare beneficiaries.<sup>70</sup>

### III. MEDICARE MANAGED CARE

HCFA has long promoted managed care for its beneficiaries and, indeed, as discussed above, was in the forefront of developing managed care techniques.<sup>71</sup> Movement toward managed care became a central theme of the Medicare program in the early 1980s. Clearly, the major theme of the regulatory approaches to cost containment, such as payment reform as well as tighter management of utilization and coverage policy were based on the theory that Medicare payment and coverage policies that simply affirmed physician decisions to order covered services was at the heart of the cost inflation problem in the Medicare program. Medicare program managers and Congress have viewed managed care as a major means of controlling such physician autonomy and its costly ramifications.

For reasons discussed below,<sup>72</sup> Congress and Medicare program managers have not acted with similar speed or enthusiasm toward moving Medicare beneficiaries into capitated HMOs or managed care plans. Such efforts were among the least developed initiatives of the current Medicare program. It is useful to speculate about the rationale for this hesitancy. It may be a belief among Medicare program managers as well as Medicare beneficiaries and their providers that HMOs may not serve well a population that has a high incidence of chronic disease and disability.

#### A. *The History of HMOs and Capitated Health Plans for Medicare Beneficiaries*

As indicated above, the Medicare program has always been and remains somewhat schizophrenic about HMOs and capitated health plans for Medicare beneficiaries. In the early years of Medicare, Congress and Medicare program managers were nervous

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M. Epstein, *The Outcomes Movement — Will It Get Us Where We Want to Go?*, 323 NEW ENG. J. MED. 266 (1990) (discussing the viability of using outcomes research to develop standards of medical treatment).

<sup>70</sup> See generally Colleen M. Grogan et al., *How Will We Use Clinical Guidelines? The Experience of Medicare Carriers*, 19 J. HEALTH POL., POL'Y & L. 7 (1994).

<sup>71</sup> See *supra* notes 60-67 and accompanying text.

<sup>72</sup> See *infra* notes 54-55 and accompanying text.

about HMOs for Medicare beneficiaries.<sup>73</sup> Even after research demonstrated that HMOs were a more efficient and cost-effective vehicle for providing medical care<sup>74</sup> and that Medicare was facing extraordinary cost inflation,<sup>75</sup> Medicare program managers and Congress were hesitant about HMOs.

In the 1960s and 1970s, congressmen from both sides of the aisle and particularly the Senate Finance Committee were concerned that the incentives for HMOs to curtail service would result in underservice to Medicare beneficiaries and enrollment of only healthy beneficiaries.<sup>76</sup> Indeed, for the most part, HMOs could only serve beneficiaries if they did so on a fee-for-service basis.<sup>77</sup>

### 1. Key Legislative Enactments

In 1972, in a major health initiative of the Nixon administration, Congress passed the Federal HMO Act to promote the development of capitated health care delivery for the non-elderly population.<sup>78</sup> One year earlier, Congress had also authorized a very restrictive capitation payment arrangement for HMOs serving Medicare beneficiaries.<sup>79</sup> This arrangement was so unattractive to HMOs that only two HMOs actually contracted with HCFA to serve Medicare beneficiaries on this basis.<sup>80</sup>

In the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Congress authorized HCFA to contract with qualified HMOs and "competitive medical plans" (CMPs) and pay them on a capitated basis.<sup>81</sup> TEFRA defined HMOs, for purposes of the Medicare program, as meeting the requirements of the Federal HMO

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<sup>73</sup> See generally John K. Iglehart, *Medicare Turns to HMOs*, 312 NEW ENG. J. MED. 132, 132-33 (1985) (discussing the movement to "marry Medicare with HMOs").

<sup>74</sup> See generally Sheldon Greenfield et al., *Variations in Resource Utilization Among Medical Specialties and Systems of Care: Results from the Medical Outcomes Study*, 267 JAMA 1624 (1992).

<sup>75</sup> See *supra* notes 12-14, 54-55 and accompanying text.

<sup>76</sup> See generally Iglehart, *supra* note 73.

<sup>77</sup> *Id.* See *infra* note 79 and accompanying text.

<sup>78</sup> Federal Health Maintenance Organization Act of 1973, Pub. L. No. 93-222, 87 Stat. 914 (codified as amended at 42 U.S.C. §§ 300(e) *et seq.* (1988)).

<sup>79</sup> See Social Security Amendments of 1972, § 226, Pub. L. No. 92-603, 86 Stat. 1329, 1396 (codified as amended at scattered sections of 42 U.S.C. § 1395mm (1988 & Supp. V 1993)); see Iglehart, *supra* note 73, at 133.

<sup>80</sup> See Iglehart, *supra* note 73, at 133.

<sup>81</sup> Pub. L. No. 97-248, § 114, 96 Stat. 324, 341 (1982) (codified as amended at 42 U.S.C. § 1395mm (1988)). In addition, pursuant to this authority, HCFA authorized health care prepayment plans (HCPPs) which could provide Part B services to beneficiaries on a prepaid basis. See 42 C.F.R. §§ 417.800-838 (1995). HCFA then would pay HCPPs on a cost reimbursement basis. *Id.* § 417.800(c).

Act<sup>82</sup> for federally qualified HMOs.<sup>83</sup> CMPs are simply capitated managed care plans that are not federally qualified HMOs under the Federal HMO Act.<sup>84</sup> The requirements for CMPs are less stringent, but must provide specified physician and other services, out-of-area coverage, and inpatient hospital services.<sup>85</sup>

HMOs and CMPs qualified to serve Medicare beneficiaries must meet federal statutory, regulatory, and contract requirements. One of the most important of these requirements is that Medicare HMOs must, with some exceptions, serve at least 5,000 individuals of which 75% are Medicare beneficiaries. Medicare HMOs must also offer the full complement of Medicare services and meet other requirements, including having comprehensive and publicized grievance and appeal procedures.<sup>86</sup>

Specifically, Congress authorized HCFA to enter into three types of contracts with Medicare HMOs—risk contracts which typically use capitated payment methods, cost contracts, and health care prepayment plans.<sup>87</sup> Since 1982, Medicare has had the authority to pay for services for its beneficiaries on a capitated basis in its Medicare HMO Risk Contractor Program.<sup>88</sup> Under a risk contract, the HMO is paid a capitated payment per patient and assumes the financial risk for the care of that patient.<sup>89</sup> To calculate the capitated rate, HCFA uses the Adjusted Average Per Capita Cost (AAPCC) which reflects the average cost of providing services to a Medicare beneficiary as adjusted for age, sex, welfare status, institutionalization, and geographic area.<sup>90</sup> HCFA sets the AAPCC annually and publishes the rate in the *Federal Register*.<sup>91</sup>

It is important to emphasize that risk-based Medicare HMOs cannot retain savings achieved through efficiencies but, rather,

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<sup>82</sup> 42 U.S.C. § 300d-9(d) (1988).

<sup>83</sup> Tax Equity and Fiscal Responsibility Act, § 114 (codified as amended at 42 U.S.C. § 1395mm(b) (1988 & Supp. V 1993)).

<sup>84</sup> Pub. L. No. 93-222, 87 Stat. 914 (codified as amended at 42 U.S.C. §§ 300(e) *et seq.* (1988)).

<sup>85</sup> See 42 C.F.R. § 417.407(c) (1995).

<sup>86</sup> See 42 C.F.R. §§ 417.600-638 (1995).

<sup>87</sup> 42 U.S.C. §§ 1395mm & l (1988); see HEALTH PLAN REQUIREMENTS GUIDE FOR MANAGED CARE AND OTHER HEALTH PLANS, at 1200:3 (Atlantic Information Servs., Inc., Nov. 1995).

<sup>88</sup> See *supra* note 81 and accompanying text.

<sup>89</sup> 42 C.F.R. § 417.584(a) (1995).

<sup>90</sup> *Id.* § 417.401; Susan J. Stayn, *Securing Access to Care in Health Maintenance Organizations: Toward a Uniform Model of Grievance and Appeal Procedures*, 94 COLUM. L. REV. 1674, 1685 (1994).

<sup>91</sup> 42 C.F.R. § 417.401; see Stayn, *supra* note 90, at 1685 (explaining the risk and cost contracts and calculation of payments for both types).

must use these savings to enhance benefits for Medicare beneficiaries.<sup>92</sup> Congress mandated this approach out of concerns that, otherwise, HMOs would cut corners in the care of Medicare HMO enrollees.<sup>93</sup> Consequently, Medicare risk-based HMOs and CMPs, while accomplishing some savings, have not achieved savings comparable to private capitated health plans.<sup>94</sup>

In 1986, Congress also imposed prohibitions on the ability of HMOs and CMPs to provide financial incentives to physicians to limit services to enrollees.<sup>95</sup> At this time, Congress also strengthened the consumer protection provisions for Medicare enrollees in HMOs and CMPs.<sup>96</sup>

## 2. The Mixed Track Record of Medicare HMOs

The track record of HMOs under the Medicare program after 1982 has been mixed. HCFA demonstrations testing the experience of Medicare beneficiaries in HMOs with risk contracts reported generally satisfactory performance by risk-based Medicare HMOs.<sup>97</sup> One demonstration found little difference in the actual experience of beneficiaries in traditional fee-for-service care and Medicare HMOs, although beneficiaries in HMOs reported less confidence in the quality of HMO physicians.<sup>98</sup> Research also demonstrated considerable satisfaction with HMOs among Medicare beneficiaries as well as increasingly high levels of quality care.<sup>99</sup>

Yet, in the 1980s, Medicare beneficiaries expressed dissatisfaction with Medicare HMOs and particularly coverage decisions made by Medicare HMOs. Specifically, Network Design Group (NDG), the private contractor that handles reconsiderations of

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<sup>92</sup> See 42 U.S.C. § 1395mm (1988 & Supp. V 1993) (regulating use of savings).

<sup>93</sup> See Iglehart, *supra* note 73, at 132-33.

<sup>94</sup> Congressional Budget Office, *Managed Care and the Medicare Program*, Medicare & Medicaid Guide (CCH) ¶ 43,208 (Apr. 26, 1995).

<sup>95</sup> See Omnibus Budget Reconciliation Act of 1986, § 9313(c), Pub. L. No. 99-509, 100 Stat. 1874, 2002 (codified as amended at 42 U.S.C. § 1320a-7a (1988)) (prohibiting financial incentives aimed at limiting services to program participants).

<sup>96</sup> See *id.* § 9312, Pub. L. No. 99-509, 100 Stat. 1874, 1999 (codified as amended at 42 U.S.C. § 1320mm (1988)) (providing consumer protection).

<sup>97</sup> See generally Sheldon M. Retchin et al., *How the Elderly Fare in HMOs: Outcomes from the Medicare Competition Demonstrations*, 27 HEALTH SERVICES RES. 652 (1992); Gregory R. Nycz et al., *Medicare Risk Contracting: Lessons from an Unsuccessful Demonstration*, 257 JAMA 656 (1987).

<sup>98</sup> See Retchin et al., *supra* note 97.

<sup>99</sup> See generally Louis F. Rossiter et al., *Patient Satisfaction Among Elderly Enrollees and Disenrollees in Medicare Health Maintenance Organizations: Results from the National Medicare Competition Evaluation*, 262 JAMA 57 (1989); Retchin et al., *supra* note 97.

HMO determinations in grievance procedures, recently reported that a major source of beneficiary dissatisfaction was coverage disputes and noted that many enrollees who appealed coverage disputes to NDG disenrolled from Medicare HMOs shortly thereafter.<sup>100</sup> DHHS data reports that almost one in three Medicare beneficiaries in HMOs disenroll within two years.<sup>101</sup>

Also, during the late 1980s, several large HMOs exhibited serious problems with respect to quality of care and consumer satisfaction which attracted considerable media and political attention.<sup>102</sup> The United States General Accounting Office (GAO) expressed concern about the rapid expansion of the Medicare HMO program and the capacity of HCFA to adequately monitor Medicare HMOs.<sup>103</sup> During this period, Congress and HCFA were also concerned about HMO incentive payments to physicians and their effect on quality of care.<sup>104</sup> As noted, Congress forbade such incentive payments to physicians.<sup>105</sup>

In 1991, the GAO issued a report about the serious problems with large HMOs as well as continued problems with Medicare HMOs and the quality of care they provide to Medicare beneficiaries.<sup>106</sup> Congressional hearings and reports revealed similar concerns.<sup>107</sup> In 1993, the Administrator of HCFA publicly an-

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<sup>100</sup> Stayn, *supra* note 90, at 1687 & n.91 (citing DAVID A. RICHARDSON, NETWORK DESIGN GROUP, INC., A STUDY OF COVERAGE DENIAL DISPUTES BETWEEN MEDICARE BENEFICIARIES AND HMOs 2, 62 (1993)).

<sup>101</sup> *Id.* & n.90 (citing LOUIS W. SULLIVAN, DEPARTMENT OF HEALTH & HUMAN SERVS., DISENROLLMENT EXPERIENCE IN THE MEDICARE HMO AND CMP RISK PROGRAM: 1985 TO 1988 FINAL REPORT ii, 43 (1990)).

<sup>102</sup> See generally John K. Iglehart, *Second Thoughts About HMOs for Medicare Patients*, 316 NEW ENG. J. MED. 1487 (1987).

<sup>103</sup> See U.S. GENERAL ACCOUNTING OFFICE, EXPERIENCE SHOWS WAYS TO IMPROVE OVERSIGHT OF HEALTH MAINTENANCE ORGANIZATIONS, No. HRD-88-73 (Aug. 18, 1988), reprinted in Medicare and Medicaid Guide (CCH) ¶ 37,242 (1988) (noting the rapid expansion of the Medicare HMO program and questioning the ability of the HCFA to effectively oversee the program).

<sup>104</sup> See U.S. GENERAL ACCOUNTING OFFICE, MEDICARE: PHYSICIAN INCENTIVE PAYMENTS BY PREPAID HEALTH PLANS COULD LOWER QUALITY OF CARE (GAO/HRD-89-29) (Dec. 1988).

<sup>105</sup> See *supra* note 95 and accompanying text.

<sup>106</sup> See U.S. GENERAL ACCOUNTING OFFICE, MEDICARE: HCFA NEEDS TO TAKE STRONGER ACTIONS AGAINST HMOs VIOLATING FEDERAL STANDARDS (GAO/HRD-92-11) (Nov. 12, 1991), reprinted in Medicare and Medicaid Guide (CCH) ¶ 39,742 (1992).

<sup>107</sup> See, e.g., *Medicare HMOs and Quality Assurance: Unfulfilled Promises: Hearings before the Senate Special Comm. on Aging*, 102d Cong., 1st Sess. (1991) [hereinafter *Medicare HMOs and Quality Assurance*]; *Medicare HMO Risk-Contractor Program: Hearings before the House Subcomm. on Health and the Environment*, 102d Cong., 1st Sess. (1991) [hereinafter *Medicare HMO Risk-Contractor Program*]; MINORITY STAFF OF SENATE SPECIAL COMM.

nounced that HCFA was not encouraging Medicare beneficiaries to enroll in Medicare HMOs because of quality concerns.<sup>108</sup>

### 3. Beneficiary Enrollment in Medicare HMO and Capitated Health Plans

The enrollment of Medicare beneficiaries in HMOs capitated health plans over the course of the program has reflected the early ambivalence about capitated health plans for Medicare beneficiaries as well as market trends. In 1985, fewer than one million Medicare beneficiaries had enrolled in Medicare HMOs.<sup>109</sup> In recent years, the number of Medicare beneficiaries enrolled in HMOs has grown considerably from 883,000 (2.9%) in 1984 to 2,238,000 (6.3%) in 1992.<sup>110</sup> An estimated 150 managed care organizations contracted with HCFA in 1995 which constituted a 40% increase from the previous year.<sup>111</sup>

It is important to appreciate that this movement of Medicare beneficiaries toward HMOs and capitated health plans is taking place without federal legislation. The movement has now taken on dramatic dimensions and it is likely that a significant proportion of Medicare beneficiaries will receive health care through capitated health plans irrespective of federal legislation. Consequently, it is crucial to revisit the procedural protections that are now in place as well as those proposed in bills before Congress for Medicare beneficiaries.

#### B. Provisions for Protecting Medicare HMO Enrollees

There are essentially two key procedural protections for enrollees in an HMO or other capitated health plan.<sup>112</sup> First are publication of the benefits, coverage policies, enrollment, and other procedures in a comprehensible and accessible form. Second are grievance and appeal procedures for enrollees to adjudicate and resolve individual disputes with the plan.

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ON AGING, 100 CONG., 1ST SESS., MEDICARE AND HMOs: A FIRST LOOK, WITH DISTURBING FINDINGS (Comm. Print 1987).

<sup>108</sup> Robert Pear, *Medicare to Stop Pushing Patients to Enter H.M.O.s*, N.Y. TIMES, Dec. 27, 1993, at A1.

<sup>109</sup> Iglehart, *supra* note 73, at 133.

<sup>110</sup> MEDICARE AND MEDICAID STATISTICAL SUPPLEMENT, *supra* note 7, at 24.

<sup>111</sup> Beth Freeman, *The Financial and Operational Mechanics of Medicare Risk Contract*, 2 CAPITATION & RISK CONTRACTING 1, 1 (Dec. 1995); *see also* Randall S. Brown et al., *Do Health Maintenance Organizations Work for Medicare?*, 15 HEALTH CARE FIN. REV. 7, 7-23 (1993).

<sup>112</sup> *See generally* Kinney, *Procedural Protections for Consumers*, *supra* note 2 (discussing Medicare capitation).



### 1. Medicare HMO Publication Procedures

Medicare HMOs and CMPs must provide adequate written descriptions of rules, procedures, benefits, fees and other charges, services and information to beneficiaries.<sup>113</sup> Further, HMOs cannot distribute marketing materials and application forms without HCFA approval.<sup>114</sup> Congress added considerably to these publication requirements in 1986 to further protection of Medicare beneficiaries.<sup>115</sup>

### 2. Medicare HMO Grievance and Appeal Procedures

The Medicare statute requires Medicare HMOs to have an appeals process.<sup>116</sup> HCFA has promulgated detailed regulations outlining these appeal procedures.<sup>117</sup> All Medicare HMOs must maintain "internal grievance procedures" described in written membership rules and clearly explained upon enrollment, involuntary disenrollment, or individual request. Appealable issues include denials of medical treatment within the HMO, authorization for outside referrals for supposedly covered services, and payment for emergency, urgent, or other care received outside the HMO. An HMO must notify a beneficiary of an adverse organization determination within sixty days. The notice must state the specific reasons for the determination and inform of the right to reconsideration. This determination is final and binding unless reconsidered.

When a reconsideration is requested, the HMO issues the final determination if it is favorable to the enrollee. If the HMO recommends a partial or complete affirmation of its original adverse determination, it must prepare a written explanation of its decision and send the entire file to HCFA. NDG, an outside contractor, handles reconsiderations on behalf of HCFA. HCFA contracted with NDG in 1989 following a lawsuit challenging the delays that many beneficiaries experienced with HCFA's handling of reconsideration requests.<sup>118</sup>

The Medicare statute makes express provision for the judicial review of beneficiaries' disputes with HMOs. If the amount in controversy is \$100 or more, the disappointed party may appeal to a

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<sup>113</sup> 42 C.F.R. § 417.428 (1995).

<sup>114</sup> *Id.*

<sup>115</sup> See *supra* note 96 and accompanying text.

<sup>116</sup> 42 U.S.C. § 1395mm(c)(5) (1988 & Supp. V); see Stayn, *supra* note 90, at 1691.

<sup>117</sup> 42 C.F.R. § 417.600-638 (1995).

<sup>118</sup> Levy v. Bowen, No. 88-3271 DT, 1989 WL 136292, at \*2 (C.D. Cal. June 20, 1989).

Social Security Administration Administrative Law Judge (ALJ). The HMO must be a party to the hearing but may not request a hearing.<sup>119</sup> The beneficiary or HMO may request an Appeals Council review of the ALJ's decision as well as judicial review if the amount in controversy exceeds \$1000.<sup>120</sup> This is essentially the system for administrative and judicial review that is available for other Medicare beneficiary disputes.<sup>121</sup>

### 3. Problems with Current Medicare HMO Procedural Protections

There have been indications of problems with HMO grievance and appeal procedures. In two congressional hearings,<sup>122</sup> consumers leveled extensive complaints about the operation of grievance procedures in HMOs. Specifically, there are several important issues regarding regularity and timeliness of appeals. These include: denials of payment for treatment by outside providers and/or emergency or urgently needed care; and inpatient care issues such as unauthorized postemergency care or pressure to discharge patients whom the HMO or its utilization reviewer believes no longer need hospital level care.<sup>123</sup>

There have been two lawsuits challenging Medicare HMO appeal procedures. In *Levy v. Sullivan*,<sup>124</sup> HCFA entered a settlement agreement to improve timeliness and notice in reconsiderations.<sup>125</sup> More recently, in *Grijalva v. Shalala*,<sup>126</sup> a federal district court certified a national class in a lawsuit alleging serious deficiencies in the Medicare HMO grievance and appeal procedures. This claim alleges that DHHS failed to monitor and sanction risk-based HMOs that failed to implement effective notice, appeals, or a contemporaneous hearing procedure for HMO service denials. Most individual claimants allege that the HMO failed to provide timely notification of the denial or that the notice, when given, inade-

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<sup>119</sup> 42 C.F.R. §§ 417.630-632 (1995).

<sup>120</sup> *Id.* §§ 417.634-636.

<sup>121</sup> See generally Eleanor D. Kinney, *The Medicare Appeals System for Payment and Coverage Disputes*, 1 ADMIN. L. J. 1 (1986) (discussing the appeals system).

<sup>122</sup> *Medicare HMOs and Quality Assurance*, *supra* note 107; *Medicare HMO Risk-Contractor Program*, *supra* note 107.

<sup>123</sup> Stayn, *supra* note 90, at 1685-87; see, e.g., *Probstein v. Sullivan*, No. Civ. H-90-18 (PCD), 1992 WL 309932 (D. Conn. Jan. 5, 1993); *Pulleyblank v. Sullivan*, No. 91-05051 (GAG), 1992 WL 163291 (D.D.C. Mar. 16, 1992).

<sup>124</sup> No. 88-3271 DT, 1989 WL 265476 (C.D. Cal. Mar. 14, 1989).

<sup>125</sup> See *supra* note 118 and accompanying text.

<sup>126</sup> Civ. No. 93-711 TUC ACM, 1995 WL 523609 (D. Ariz. Jul. 18, 1995).

quately stated the reason. Additionally, the claimants complain of insufficient notice of appeal rights and ineffective appeals process.

The subject of coverage and adequate procedures to appeal coverage denials is a difficult issue with respect to HMOs and managed care plans.<sup>127</sup> As cost concerns increase, HMOs and managed care plans may well be under great pressure to make restrictive coverage decisions in the care of Medicare beneficiaries. Further, beneficiaries may not recognize these coverage decisions as such because they are often couched in physicians' clinical decisions and will not be presented in the context of a claim as occurs under traditional fee-for-service medical care. It is crucial to revisit Medicare appeal procedures for both Part B and Medicare HMOs to ensure that beneficiaries have adequate procedures to challenge coverage denials in managed care systems.

#### IV. LEGISLATIVE PROPOSALS: FROM MEDICARE TO CAPITATED MANAGED CARE

The 1990s have seen unprecedented congressional interest in the reform of the health care system from across the ideological spectrum.<sup>128</sup> President Clinton introduced the Health Security Act of 1993<sup>129</sup> to provide comprehensive health reform based on principles of managed competition.<sup>130</sup> Several senators and members of Congress introduced health reform bills as well.<sup>131</sup> One bill to establish a single-payer system would have expanded the Medicare program to cover all Americans.<sup>132</sup> In most bills before the 103d Congress, the Medicare program was essentially unchanged.<sup>133</sup> The President and congressmen were concerned that undue tampering with the Medicare program would anger elderly voters.<sup>134</sup>

With the election of Republican majorities in the House and Senate in 1994, the health reform landscape changed dramatically. Proposals for comprehensive health reform were long forgotten. The Republican Congress turned to the Medicare program as a way to meet its paramount goal of balancing the federal budget in

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<sup>127</sup> See generally Kinney, *Resolving Consumer Grievances*, *supra* note 2; Kinney, *Procedural Protections for Consumers*, *supra* note 2; Kinney, *Protecting Consumers and Providers*, *supra* note 2.

<sup>128</sup> See Kinney, *Protecting Consumers and Providers*, *supra* note 2, at 83-89.

<sup>129</sup> H.R. 3600, 103d Cong., 1st Sess. (1993).

<sup>130</sup> See generally Alain C. Enthoven, *The History and Principles of Managed Competition*, 12 HEALTH AFF. 24 (Supp. 1993).

<sup>131</sup> Kinney, *Protecting Consumers and Providers*, *supra* note 2, at 83-86.

<sup>132</sup> See H.R. 1200, 103d Cong., 1st Sess. (1993).

<sup>133</sup> See Kinney, *Protecting Consumers and Providers*, *supra* note 2, at 114-16.

<sup>134</sup> See *id.*

seven years. All proposals before the 104th Congress would move Medicare beneficiaries toward capitated managed care plans.<sup>135</sup>

A. *The Republican Proposal*

The Republican proposal, the Medicare Preservation Act of 1995,<sup>136</sup> would contain a number of incentives for Medicare beneficiaries to enroll in capitated health plans while leaving open the option, albeit more expensive, to remain in traditional fee-for-service care. The bill also contains a radical proposal for MedicarePlus plans which would enable Medicare beneficiaries to obtain health insurance through the private market in capitated health plans.<sup>137</sup>

MedicarePlus plans can be quite varied in design and may offer a medical savings account feature through which beneficiaries can retain savings if all account funds are not used for medical expenditures.<sup>138</sup> Also MedicarePlus plans can be sponsored by a variety of organizations that provide health coverage in the private market.<sup>139</sup> The Secretary of DHHS is responsible for certifying plans and may do so in conjunction with comparable state programs.<sup>140</sup>

The Secretary of DHHS is also responsible for developing standards for MedicarePlus organizations.<sup>141</sup> In so doing, the Secretary must consult with the National Association of Insurance Commissioners (NAIC).<sup>142</sup> Further, the Secretary must initiate a negotiated rulemaking process to develop these standards through a consensus of affected parties.<sup>143</sup>

The Republican proposal places great emphasis on publication of information about the plans. The Secretary would be responsible for broadly disseminating information to current and prospective Medicare beneficiaries on the coverage options avail-

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<sup>135</sup> See generally Beth C. Fuchs et al., *Medicare: the Restructuring Debate*, CRS ISSUE BRIEF, Order Code IB95108 (1995); THE TWENTIETH CENTURY FUND, *MEDICARE REFORM: A TWENTIETH CENTURY FUND GUIDE TO THE ISSUES* (1995).

<sup>136</sup> H.R. 2425, 104th Cong., 1st Sess. (1995). For an excellent review of the Republican Medicare proposal, see generally CONGRESSIONAL RESEARCH SERVICE, *SUMMARY OF THE MEDICARE PRESERVATION ACT OF 1995* (1995).

<sup>137</sup> See H.R. 2524, § 15001 (creating Social Security Act [hereinafter SSA] § 1805(a)).

<sup>138</sup> See *id.* § 15011.

<sup>139</sup> See *id.* § 15002 (creating SSA §§ 1851 & 1854).

<sup>140</sup> *Id.* (creating SSA § 1857).

<sup>141</sup> *Id.* (creating SSA § 1856).

<sup>142</sup> *Id.* (creating SSA § 1856(a)(1)).

<sup>143</sup> *Id.* (creating SSA § 1856(c)(1)).

able in order to encourage informed selection.<sup>144</sup> The Secretary would be required to provide, at a minimum: (1) an information booklet during coverage election periods which includes standardized information regarding premiums, quality (including customer satisfaction), beneficiary rights, and responsibilities; (2) a toll-free number for inquiries; and (3) information in the Medicare Handbook regarding the MedicarePlus option.<sup>145</sup>

The legislation would create a new congressional commission, the Medicare Payment Review Commission, to review and make recommendations to Congress concerning payment policies.<sup>146</sup> The Secretary of DHHS would be required to respond to Commission recommendations in an informal rulemaking process.<sup>147</sup> The Commission would be responsible for determining the following: the appropriateness of payment methodologies and risk adjustment factors for MedicarePlus plans; the implications of risk selections; development and implementation of quality assurance strategies for MedicarePlus plans and the impact of MedicarePlus plans in beneficiary access to care.<sup>148</sup> The Commission would also have the responsibility of reviewing payment policies for fee-for-service providers under Parts A and B of the Medicare program.<sup>149</sup> This Commission would replace the congressional commissions that now review Medicare hospital and physician payment policies.

Each MedicarePlus organization would have to provide for meaningful procedures for hearing and resolving grievances between the organization (and entities and individuals through which it provides services) and enrollees.<sup>150</sup> Regarding appeals of coverage determinations, each MedicarePlus organization would have to make determinations regarding authorization requests for nonemergency care on a timely basis.<sup>151</sup> Medical necessity decisions could only be made by a physician.<sup>152</sup> Appeals of a determination would be required within thirty to sixty days of receiving relevant medical information.<sup>153</sup>

An enrollee dissatisfied by reason of the enrollee's failure to receive health services would be entitled, if the amount in contro-

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<sup>144</sup> *Id.* (creating SSA § 1805(d)(1)).

<sup>145</sup> *Id.* (creating SSA § 1805(d)(3)).

<sup>146</sup> *Id.* § 15031.

<sup>147</sup> *Id.* (creating SSA § 1806(b)(1)(D)).

<sup>148</sup> *Id.* (creating SSA § 1806(b)(2)).

<sup>149</sup> *Id.* (creating SSA § 1806(a)(4)).

<sup>150</sup> *Id.* § 15002 (creating SSA § 1853(f)(1)).

<sup>151</sup> *Id.* (creating SSA § 1853(e)(1)).

<sup>152</sup> *Id.* (creating SSA § 1883(e)(2)(B)).

<sup>153</sup> *Id.* (creating SSA § 1853(e)(2)(A)).

versy was \$100 or more, to a hearing before the Secretary.<sup>154</sup> If the amount in controversy was \$1,000 or more, the individual or organization, upon notifying the other party, would be entitled to judicial review.<sup>155</sup> The Secretary would be required to contract with an independent, outside entity to review and resolve appeals of denials of coverage related to urgent or emergency services with respect to MedicarePlus products.<sup>156</sup>

The Republican proposal also sharply reduces federal expenditures for the Medicare program through increased cost sharing on the part of Medicare beneficiaries—particularly for those opting to receive care from fee-for-service Medicare providers and not through a MedicarePlus plan.<sup>157</sup> These reductions and incentives have raised the most serious concerns among advocates and providers.<sup>158</sup>

The chief concern is that the Republican proposal will encourage more healthy beneficiaries to opt for MedicarePlus plans. On the other hand, sicker and disabled beneficiaries with established relationships with providers will opt for the traditional fee-for-service Medicare program. The concern is that sicker beneficiaries will be squeezed with the larger cost-sharing requirements of fee-for-service approaches and that federal expenditures for this component of the program will increase at greater rates than expenditures for the MedicarePlus component.<sup>159</sup> While the American Medical Association ultimately supported the Republican proposal upon gaining concessions with respect to fraud and abuse, antitrust, and malpractice provisions, the American College of Physicians has launched a formal program to lobby against the Republican proposal because of these concerns.<sup>160</sup>

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<sup>154</sup> *Id.* (creating SSA § 1853(f)(2)).

<sup>155</sup> *Id.*

<sup>156</sup> *Id.* (creating SSA § 1853(f)(3)).

<sup>157</sup> *Id.* §§ 15611-12.

<sup>158</sup> *Medicare: Perspectives on the Past and Implications for the Future: Hearing on S. 104-266 Before the Senate Comm. on Finance*, 104th Cong., 1st Sess. (1995) (statement of Dr. Gail Wilensky, Senior Fellow, Project Hope, Bethesda, MD); *Medicare Provisions in the President's Budget: Hearing on S. 104-31 Before the Subcomm. on Health of the House Comm. on Ways and Means*, 104th Cong., 1st Sess. (1995) (statements of Thomas A. Scully, President and CEO, Federation of American Health Systems, and Jake Hansen, Director of Government Affairs, The Seniors Coalition).

<sup>159</sup> See Statement of Marilyn Moon, *supra* note 9; Statement of Bruce Vladeck, *supra* note 9.

<sup>160</sup> Letter from Gerald E. Thompson, President, to American College of Physician Colleagues (Aug. 15, 1995).

*B. President Clinton's Proposal*

President Clinton's proposal to reform Medicare has not been reduced to a bill but, rather, remains in specifications for legislation.<sup>161</sup> Like the Republican bill, the President's proposal would expand options for Medicare beneficiaries to enroll in managed care plans.<sup>162</sup> Further, program design should ensure that benefits, quality, and access will be comparable to current plan and that out-of-pocket expenditures will be no more than for fee-for-service Medicare.<sup>163</sup>

Plan beneficiaries are to be protected from financial instability of the plan or provider. They should have access to timely and fair resolution of appeals, grievances, and complaints. Beneficiaries are to have access to comprehensive, understandable information about plans, including basic policies and procedures, consumer satisfaction, and plan performance.<sup>164</sup> Beneficiaries are not to be coerced into any plan or prevented from enrolling in the plan of their choice due to health status. Medical records and claims information should be protected. Purchasers of services for beneficiaries will be accountable for the monitoring of these protections.<sup>165</sup>

The President's proposal contains no express provisions pertaining to grievance procedures. Presumably, beneficiaries would use existing procedures.<sup>166</sup>

#### V. PROTECTING MEDICARE BENEFICIARIES IN MANAGED CARE PLANS

As Medicare moves toward capitated managed care in an era of budget reductions, it is crucial to understand the ways to protect the legitimate interests of Medicare beneficiaries in getting high quality medical care. Although it is beyond the scope of this Article to critique substantively the legislative proposals currently before Congress, it is crucial to appreciate that the ultimate protection of Medicare beneficiaries comes from a well-designed program.

To that end, design incentives—such as those in the Republican legislative proposal—that promote segmentation of more

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<sup>161</sup> See PRESIDENT'S MEDICARE PROPOSAL (Draft 1995).

<sup>162</sup> See *id.*

<sup>163</sup> See *id.*

<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

<sup>166</sup> See *supra* notes 119-21 and accompanying text.

healthy beneficiaries into capitated plans while forcing more ill beneficiaries to remain in fee-for-service plans with greater cost sharing are undesirable. Further, design incentives should not freeze a minimum level of public contribution for services with the expectation that beneficiaries wanting more services or a higher level of quality of care should purchase such care independently. Such a design approach could well lead to a lean program for poorer beneficiaries while more affluent beneficiaries, who have the requisite clout to articulate the concerns of beneficiaries in the political arena, could opt out over time. Quite simply, a well-designed program should contain design incentives that prevent segmentation of the Medicare population between the sick and the healthy as well as the rich and the poor.

Nevertheless, procedural protections are important. To that end, revisiting first principles of administrative law may be instructive in dealing with new challenges of protecting beneficiaries of a government program in a new age and, specifically, in ensuring accountability of the stewards of the Medicare program and the capitated health plans with which they contract to provide care.<sup>167</sup> The protections accorded by rule and policy-making, adjudication, and judicial review are key processes in ensuring such accountability.

#### A. Medicare Program Policy-making

The Federal Constitution accords little protection to beneficiaries of a government health insurance program in terms of defining the content of benefits since the Supreme Court has clearly established that an interest in health care services is not a constitutionally protected interest.<sup>168</sup> Beneficiaries can only look to statutes for the delineation of a legally protected interest in health care service.

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<sup>167</sup> See generally Marc A. Rodwin, *Managed Care and Consumer Protection: What Are the Issues?*, 26 SETON HALL L. REV. \_\_\_\_ (1996).

<sup>168</sup> See *Harris v. McRae*, 448 U.S. 297 (1980) (holding that the funding restrictions in the Hyde Amendment to the Social Security Act do not violate the First or Fifth Amendments); *Maier v. Roe*, 432 U.S. 464 (1977) (holding that the Equal Protection Clause does not require a participating state in Medicare program to fund services incident to nontherapeutic abortion where state chooses to fund childbirth); see generally James Blumstein, *Distinguishing Government's Responsibility in Rationing Public and Private Medical Resources*, 60 TEX. L. REV. 899 (1982); James Blumstein, *Rationing Medical Resources: A Constitutional, Legal, and Policy Analysis*, 59 TEX. L. REV. 1345 (1981); Rand E. Rosenblatt, *Rationing "Normal" Health Care: The Hidden Legal Issues*, 59 TEX. L. REV. 1401 (1981); Rand E. Rosenblatt, *Rationing "Normal" Health Care Through Market Mechanism: A Response to Professor Blumstein*, 60 TEX. L. REV. 919 (1982).



Consequently, statutory definitions of benefits and their amount, duration, and scope are critical, though not dispositive. The Medicare statute clearly lists benefits which remain essentially the same under all reform proposals.<sup>169</sup> Perhaps more important are statutory definitions and, more particularly, standards governing coverage of benefits. As indicated above,<sup>170</sup> coverage can be an extremely flexible concept, particularly when interpreted in the context of capitated health plans. The details of amount, duration, and scope of services are probably best delineated in manuals and other nonlegislative program guidance as HCFA now does.<sup>171</sup>

The statute should still enunciate standards for coverage that are enforceable in court when not followed by program administrators or their contractors. Currently, the major statutory standards for coverage are "reasonable and necessary" for the diagnosis and treatment of disease and injury.<sup>172</sup> As indicated above, even these general standards of coverage have been controversial.<sup>173</sup>

A statutory coverage standard alone is not sufficient to ensure that Medicare will pay only for necessary services while protecting the interests of beneficiaries of those services. The policy or standard must also be enforced in good faith without seeking to accomplish other goals such as cost containment.

The controversy over coverage policy for home health services in the late 1980s is a case in point. HCFA, to curve the sharply escalating costs of home health care for the Medicare program, instructed fiscal intermediaries to the statutory requirements that home health care be provided on an intermittent basis.<sup>174</sup> Fiscal intermediaries began denying claims for home health services on a retroactive basis, raising cries of unfairness among home health agencies and Medicare beneficiaries.<sup>175</sup> In response, Congress held numerous hearings.<sup>176</sup>

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<sup>169</sup> See *supra* notes 21-30 and accompanying text.

<sup>170</sup> See *supra* note 100 and accompanying text.

<sup>171</sup> See Kinney, *The Medicare Appeals System*, *supra* note 2, at 9-10.

<sup>172</sup> See *supra* notes 33-34 and accompanying text.

<sup>173</sup> See *supra* notes 39-43 and accompanying text.

<sup>174</sup> See Kinney, *In Search of Bureaucratic Justice*, *supra* note 2, at 254 (offering a background of the Medicare Home Health Benefit).

<sup>175</sup> *Id.* at 259-68.

<sup>176</sup> See, e.g., *Home Health Care: The Agony of Indifference: Hearings Before the Senate Special Comm.*, 100 Cong., 1st Sess. (1987); HOUSE SELECT COMM. ON AGING, THE ATTEMPTED DISMANTLING OF THE MEDICARE HOME CARE BENEFIT: A REPORT TO THE CHAIRMAN OF THE SUBCOMM. ON HEALTH AND LONG-TERM CARE, 99th Cong., 2d Sess. (1986).

Ultimately, in *Duggan v. Bowen*,<sup>177</sup> home health agency advocates, Medicare beneficiaries, home health agencies, and several members of Congress filed suit claiming constitutional and statutory violations in HCFA's execution of coverage policy for Medicare home health benefits. The United States District Court for the District of Columbia ruled in favor of the plaintiffs.<sup>178</sup> The lawsuit was settled when HCFA agreed to revise its coverage policy in program manuals to be less restrictive and accord greater flexibility to fiscal intermediaries in applying coverage standards.<sup>179</sup> Following this revision of coverage policy, Medicare expenditures for home health care increased sharply and now constitutes one of the fastest growing categories of Medicare spending.<sup>180</sup>

The lesson from this experience is that statutory coverage standards are not able to serve as cost-containment vehicles because, when applied restrictively, they unduly curtail discretion and harm beneficiaries. The stewards of the Medicare program appreciate this fact and, thus, have pushed for the development of coverage policy that more clearly reflects the consensus of the medical and scientific community as to efficacy of specific services and treatment modalities.<sup>181</sup> Further, other cost containment strategies are needed, such as altering retrospective cost- or charged-based payment policies, to change the tendency of providers to maximize the amount of services provided to individual beneficiaries. HCFA has moved to prospective payment systems for most providers to address such incentives.<sup>182</sup> It is considering similar payment reforms for home health agencies.<sup>183</sup>

In sum, having statutory coverage standards coupled with coverage policy for specific services that are scientifically based is essential to protect the legitimate interests of beneficiaries. Further, implementation of coverage policy should not be used as a cost-containment methodology. Rather, HCFA should modify payment methodologies to address cost-containment concerns. To be sure that coverage policy is scientifically based and reflects the consen-

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<sup>177</sup> 691 F. Supp. 1487 (D.D.C. 1988).

<sup>178</sup> See *id.* (holding that the Department of Health and Human Services interpretation of part-time or intermittent care contravened statute which specifically excluded only full-time care from coverage).

<sup>179</sup> See HEALTH CARE FIN. ADMIN., MEDICARE HOME HEALTH AGENCY MANUAL, at Transmittal No. 222 (April 1989).

<sup>180</sup> Levit et al., *supra* note 6, at 265.

<sup>181</sup> See *supra* notes 66-70 and accompanying text.

<sup>182</sup> See *supra* notes 64-65 and accompanying text.

<sup>183</sup> Bruce E. Vladeck, Ph.D. & Nancy A. Miller, Ph.D., *The Medicare Home Health Initiative*, 16 HEALTH CARE FIN. REV. 7, 12-13 (1994).

sus of the medical community about the quality of care, coverage must be made in an open, regular process. HCFA's coverage policy-making process has been criticized as inaccessible and irregular in the 1980s.<sup>184</sup> In recent years, however, HCFA has publicized how it makes coverage policy<sup>185</sup> and this process has generated less controversy.

Further, research sponsored by HCFA and AHCPR on the efficacy and outcomes of specific medical procedures should be selected and funded in a credible process. Currently, HCFA and AHCPR use peer review by independent experts to select projects for funding following open proposal solicitations. The process for supervising the research that supports Medicare coverage policy has enjoyed respect and support in the medical and policy communities.

Another substantive area in which policy and policy-making is of crucial importance—particularly as Medicare moves to capitated managed care—is quality assessment and improvement. In Medicare's early years, quality of care was left chiefly to providers and Medicare relied on private accreditation and state licensure to determine that a particular provider was capable of providing services of acceptable quality to Medicare beneficiaries.<sup>186</sup> However, as Medicare moves to payment systems that shift the financial risk of providing excess services from the program to the provider—as is the case with prospective payment and especially capitation—the Medicare program must take greater responsibility for monitoring the quality of services. With the shift in risk, incentives now exist for providers to curtail services inappropriately to achieve savings.

HCFA has moved aggressively to improve its monitoring of quality of services to Medicare beneficiaries. When Medicare moved to prospective payment for hospitals, Congress established the Peer Review Program to monitor provider behavior under that new payment system.<sup>187</sup> Over the years, Congress has added to the quality assurance and improvement functions of PROs.<sup>188</sup> Subsequently, HCFA became an inspiring force in the move to evaluat-

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<sup>184</sup> See *supra* notes 39-43 and accompanying text.

<sup>185</sup> See *supra* notes 35-38 and accompanying text.

<sup>186</sup> See generally Eleanor D. Kinney, *Private Accreditation as a Substitute for Direct Government Regulation in Public Health Insurance Programs: When is it Appropriate?*, 57 L. & CONTEMP. PROBS. 47 (1994) (exploring the option of private accreditation of Medicare providers as an alternative to government monitoring of program providers).

<sup>187</sup> See *supra* note 62 and accompanying text.

<sup>188</sup> See Timothy S. Jost, *Administrative Law Issues Involving the Medicare Utilization and Quality Control Peer Review Organization (PRO) Program: Analysis and Recommendations*, 50 OHIO ST. L.J. 1, 30-53 (1989) (addressing the quality assurance and sanction pro-

ing quality and efficacy of care on the basis of outcomes of care.<sup>189</sup> Further, over the years, HCFA has embraced principles of total quality management and continuous quality improvement as a means of improving the care of Medicare beneficiaries.<sup>190</sup> These modern theories of quality management borrowed from industry have completely changed the way in which health care providers conceptualize processes for assessing and improving the quality of health care.<sup>191</sup> HCFA is now developing a system of outcome measures for capitated managed care that are widely used in Medicare HMOs, Medicaid managed care plans, and private capitated health plans.

In sum, policies and policy-making are the first line of defense, so to speak, in protecting the legitimate interests of Medicare beneficiaries. Sound substantive policy and standards are essential and ultimately provide the requisite guarantees of full benefits and high-quality services for beneficiaries in the event of deprivation in individual cases. Without sound policies and standards, individuals have little on which to rely in administrative appeals or judicial review.

The two most important areas of substantive policy for the Medicare program are the coverage and quality of health care services provided to Medicare beneficiaries. Benefits and coverage policy defines the content of services and quality policy and standards address the quality of these services. Together, coverage and quality policy and standards address pressures that capitated health plans have to constrain costly health care services or otherwise cut corners in ways that compromise quality of care.

It is noteworthy that the Republican legislative proposal contains a provision for the publication of coverage and quality policy and standards.<sup>192</sup> The President's proposal, in particular, contains extensive provisions for quality policy and standards and their

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gram, its criticisms and major areas of concern, and exploring two alternative means of improving the sanction process).

<sup>189</sup> See *supra* note 67 and accompanying text.

<sup>190</sup> See *infra* note 191 and accompanying text.

<sup>191</sup> See generally TROYEN A. BRENNAN & DONALD M. BERWICK, *NEW RULES: REGULATION, MARKETS, AND THE QUALITY OF AMERICAN HEALTH CARE* (1996); DONALD M. BERWICK ET AL., *CURING HEALTH CARE: NEW STRATEGIES FOR QUALITY IMPROVEMENT* (1990); Glenn Laffel & David Blumenthal, *The Case for Using Industrial Quality Control Management Science in Health Care*

*Organizations*, 262 JAMA 2869 (1989); see also Donald M. Berwick, *Continuous Improvement as an Ideal in Health Care*, 320 NEW ENG. J. MED. 53, 53-56 (1989); Donald M. Berwick, *Controlling Variation in Health Care: A Consultation from Walter Shewhart*, 29 MED. CARE 1212, 1214 (1991).

<sup>192</sup> See H.R. 2524, *supra* note 138.

monitoring.<sup>193</sup> The content of both proposals clearly addresses coverage and quality issues appropriately. However, the key with all legislated policy and standards lies with the good faith and energy with which they are enforced.

The central concern with the Medicare program is whether governmental pressures to contain Medicare expenditures and reduce the federal budget deficit will unduly influence HCFA and its contractors in implementing the Medicare program. In that event, expenditure control goals will become paramount and possibly result in restrictive coverage interpretations and a lessening of quality controls to the detriment of Medicare beneficiaries. To curb these trends, the procedural protections of administrative adjudication and judicial review are crucial.

### *B. Adjudication Procedures*

Adjudication procedures, which include grievance procedures, are an important means of protecting the legitimate interest of beneficiaries in health care services financed by the Medicare program. Such procedures are essential to empowering beneficiaries with the capability of enforcing accountability of the program on matters of direct concern. These procedures are also the only practical and accessible way to resolve disputes between beneficiaries and managed care plans which, in reality, make the critical coverage decisions and control quality for all individual beneficiaries in the day-to-day course of clinical care.

There are certain principles that guide the design and operation of patient protection mechanisms in any managed care plan, which I have described and discussed in greater detail in other articles I have written on administrative procedures under health reform and managed care.<sup>194</sup> Basically, these principles are as follows: any procedure is appropriate *provided* that certain procedural elements are present. There are four key elements.

First, there should be timely notice that appealable events have occurred and of the procedures for appeals. This includes notice of applicable medical practice guidelines that govern coverage under the plan. Second, there should be prompt decisions by a knowledgeable, unbiased decision-maker. In any adjudication system, speed and expertise in the decision-making process are key to providing genuine relief. Third, large areas for the exercise of

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<sup>193</sup> See PRESIDENT'S MEDICARE PROPOSAL, *supra* note 164.

<sup>194</sup> See generally Kinney, *Protecting Consumers and Providers*, *supra* note 2; Kinney, *Procedural Protections for Consumers*, *supra* note 2.

discretion should be accorded to the decision maker. Although counterintuitive, decision makers need to have the latitude to provide satisfactory relief to an appellant. Hard and fast rules on coverage, for example, imposed more constraints on payers as well as on the clinical decisionmaking of physicians within the plan.

Finally, and perhaps most importantly, there should be methods for empowering patients in the grievance process. This is a troubling issue given the inherent disparity between patients and plans in terms of power and expertise. A grievance procedure should be informal and comprehensible enough that patients can negotiate on their own behalf. However, the patient should have the option of retaining counsel or other representation.

These principles are especially important in the case of Medicare beneficiaries because of the characteristics of the Medicare population. Specifically, Medicare beneficiaries are either elderly, severely disabled, or very sick (in the case of beneficiaries with End Stage Renal Disease). In any event, they are heavy users of health care services and are often, because of illness and infirmity, disadvantaged when it comes to protecting their access to health care services in the health care system.

The current procedures for grievance resolution and administrative appeals are well-designed in most respects. The system requires HMOs to have an informal grievance procedure in which HCFA ostensibly has no interest.<sup>195</sup> However, there is a reconsideration process for decisions reached in grievance procedures in which HCFA does have an interest and which is completely separated from the HMO.<sup>196</sup> Although criticized in recent litigation<sup>197</sup> as being untimely, this process is an important safeguard for beneficiaries who seek to challenge decisions regarding their Medicare benefits without resorting to further administrative process or judicial review. Further, the same system of administrative review for beneficiaries in Medicare HMOs and CHPs as for fee-for-service Medicare<sup>198</sup> allows for comparable treatment of all Medicare beneficiaries as well as consistent agency review of challenged policy and other issues.

The grievance procedures and administrative review provisions of the Republican legislative proposal<sup>199</sup> contain many of the

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<sup>195</sup> Kinney, *Resolving Consumer Grievances*, *supra* note 2, at 100-01.

<sup>196</sup> See *supra* notes 117-18 and accompanying text.

<sup>197</sup> See *supra* notes 124-26 and accompanying text.

<sup>198</sup> See *supra* notes 119-21 and accompanying text.

<sup>199</sup> See *supra* notes 150-53 and accompanying text.

same important protections as the current Medicare system for Medicare HMOs, including independent reconsideration and administrative review.<sup>200</sup> Under the President's proposal, current reconsideration and administrative and judicial review procedures would remain.<sup>201</sup>

The challenge for any dispute resolution system for the Medicare program in the coming years is funding and resources. Put simply, will the stewards of the Medicare program, in the midst of straining to reduce Medicare program expenditures, devote the requisite resources to ensure that Medicare beneficiaries have access to a dispute resolution system that resolves disputes in a timely and fair manner? In short, with the Medicare program in a time of budgetary constraints, resources and official commitment rather than statutory language delineating a process will determine whether Medicare beneficiaries obtain justice in the resolution of their disputes.

### C. *Judicial Review*

Another key issue is the degree to which consumers and providers may challenge decisions and policies of a Medicare health plan in state and/or federal court. To many consumers and providers, judicial review is perceived as the ultimate forum for assuring accountability of government or corporate actors. Further, courts have played a strong role in protecting rights of consumers with respect to government entitlement programs in the past.<sup>202</sup>

Nevertheless, there are limits to what judicial review can accomplish in the protection of the legitimate interest of beneficiaries in covered Medicare benefits. Specifically, judicial review is an especially ineffective means of changing policy.<sup>203</sup> Indeed, since the Supreme Court's decision in *Chevron v. Natural Resource Defense Council*,<sup>204</sup> the Supreme Court has sharply curtailed the scope of review for federal courts in evaluating agency interpretations of their enabling legislation. But even before *Chevron*, the federal courts were reluctant to second-guess Medicare policy and generally deferred to HCFA interpretations upon judicial review.<sup>205</sup>

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<sup>200</sup> See *supra* notes 154-56 and accompanying text.

<sup>201</sup> See *supra* note 166 and accompanying text.

<sup>202</sup> See generally Rand E. Rosenblatt, *The Courts, Health Care Reform, and the Reconstruction of American Social Legislation*, 18 J. HEALTH POL., POL'Y & L. 439 (1993).

<sup>203</sup> Eleanor D. Kinney, *Rule and Policy Making under Health Reform*, 47 ADMIN. L. REV. 403, 423 (1995).

<sup>204</sup> 467 U.S. 837 (1984).

<sup>205</sup> See Kinney, *The Role of Judicial Review*, *supra* note 2, at 765-74 (detailing the ex-

Judicial review still plays a crucial role in protecting consumers in getting the amount, duration, and scope of benefits which carefully crafted statutory benefits language and coverage standards establish. Without judicial review, individual beneficiaries will have no recourse when managed care plans, in an effort to contain expenditures, restrictively interpret coverage policy and attempt to limit services for beneficiaries. Further, they would have no recourse if managed care plans do not comport with quality standards except to the extent that quality breaches constitute medical malpractice and give rise to a common law tort claim. In sum, judicial review is an important mechanism available to beneficiaries to ensure that the stewards of the Medicare program and the managed care plans with which Medicare contracts to provide services are accountable to all statutory standards and requirements designed to provide Medicare beneficiaries with health care services of high quality.

#### VI. CONCLUSION

The years ahead will inevitably see a move toward capitated managed care for Medicare beneficiaries. This move, although appropriate from the perspective of addressing many of the inefficiencies of fee-for-service medicine which promoted overutilization of costly services in many instances, must be accomplished with care. To protect beneficiaries, the major objective in this transition must be the promotion of high quality services for all beneficiaries.

Procedural protections for individual beneficiaries such as rule and policy making procedures, grievance procedures, and judicial review can only achieve beneficial outcomes if: (1) the underlying design of the program is sound; (2) the statute, regulations, and program policies faithfully convey that underlying design; and (3) the stewards of the program and their contractors faithfully implement the program.